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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,322	12/15/2005	Per Mansson	MANS3010/REF	3648

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,322	MANSSON ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-18* is/are pending in the application.

4a) Of the above claim(s) *8-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/30*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 30 December 2008 has been entered.

Status of the Claims

2. Claims 1-6 and 8-18 are currently pending in this application. Claims 8-11 have been withdrawn. Claims 1-6 and 12-18 are examined.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 30 December 2008 is considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 5, 6, 12, 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura et al. (US 2002/0009812) in view of Jacobs et al. (US 6,905,816) further in view of Tao et al. (US 2002/0121314).

Miura et al. teach a coated metal surface on a solid support (thin metal film formed on a prism support, par. 6); the coating consisting of a protein layer firmly attached to the metal surface (BSA, par. 22 and 43) and the protein layer coupled to linker molecules that are bound to low molecular weight antigens (par. 22 and 50; antigens are low molecular weight, par. 41), wherein the linker molecules are coupled to the protein layer and are bound to the antigen (par. 105-110), and wherein the antigens are reversibly bound to antibodies specific for the antigens wherein the antibodies are more weakly bound to the immobilized antigens than an analyte antigen to be tested for displacement of the antibody from the immobilized antigen (antibodies are bound to antigens on substrate, and are reversibly bound because the antibodies can be displaced during a competition assay and therefore the antibodies are more weakly bound than an analyte because the antibodies can be displaced by the analyte, par. 81).

Miura differs from instant claims in failing to teach the linker specifically having functional end groups attached to the protein and the antigen and the linker between the functional end groups having an aliphatic hydrocarbon chain of 1, 2 or 3 carbon atoms.

Jacobs teaches a protein layer on a substrate surface (BSA coating, col. 16, lines 26-40 and 53-67) linker having functional end groups (NHS-Y-NHS connects amine surface with amine-group containing molecule, col. 17, lines 5-15, Jacobs et al. does not specify with the connecting linker Y is), in order to provide an easy and low cost alternative to providing a number of tests.

And, Tao teaches a protein immobilized directly on a metal substrate (par. 158) and the proteins being capture ligands (par. 155) that bind indirectly to a ligand through capture extender ligands (par. 153), wherein the extender ligands are homo or hetero attachment linkers wherein the linker between the functional end groups is ethylene glycol or a short alkyl group which are aliphatic hydrocarbon chain with 2 and 1 carbon atoms, respectively (par. 156; target sequence attaches to capture probe via attachment linker, par. 12 and 13), in order to provide indirect attachment of the target analyte to a capture ligand.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the linker on the solid support of Miura et al., a bifunctional linker having two functional end groups as taught by Jacobs et al., in order to easily attach an antigen to a substrate having a protein by converting the chemical reactivity of the substrate surface. It would have further been obvious to one having ordinary skill in the art to include as the linker between bi-functional end groups of Miura et al. in view of Jacobs et al., an ethylene glycol or short alkyl group that each of which has an aliphatic hydrocarbon chain encompassed by the recited 1, 2 or 3 carbon atoms as taught by Tao et al., in order to provide a short linker that avoids perturbations in a binding ligand.

Regarding claims 2 and 18, Miura et al. teach the metal selected from gold, silver, aluminum and nickel (par. 48).

With respect to claims 3, 5 and 15, Miura et al. teach the same antigens bound to the same protein layer (Fig. 13; par. 79 and 80) and the antigen being a narcotic that is cocaine or methamphetamine (par. 41).

Regarding claims 17 and 18, Miura et al. teach the antibody being a monoclonal antibody (BSA is a monoclonal antibody, par. 81) and do not specifically teach how the antibody is produced or the affinity to the antigen. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 18 is for any particular purpose or solve any stated problem, and the prior art teaches that the affinity of an antibody for an antigen may be varied depending on the desired affinity required for displacement. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the displacement assay art. Although Miura et al. do not teach the specific method of production of the monoclonal antibodies, such a limitation is drawn to a method of making and only the final product must read on the

instant claims. The device taught by Miura et al. in view of Jacobs et al. further in view of Tao et al. teach the required product limitations and a monoclonal antibody and therefore reads on the instant claims.

2. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura et al. (US 2002/0009812) in view of Jacobs et al. (US 6,905,816) further in view of Tao et al. (US 2002/0121314), as applied to claims 1 and 12, further in view of Houser et al. (US 2003/0162987).

Miura et al. in view of Jacobs et al. further in view of Tao et al. teach a coated metal surface having a protein layer and an antigen that is a narcotic, but fail to teach the antigen being an explosive.

Houser et al. teach a surface plasmon resonance assay wherein a quartz slide is coated with metal (par. 50) and a sensing film is coated on the metal coated glass slide (par. 16), wherein TNT is the detected antigen (par. 14), in order to provide accurate detection of an explosive in a sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as an antigen in the device of Miura et al. in view of Jacobs et al. further in view of Tao et al., an antigen that is TNT as taught by Houser et al., in order to provide detection of a toxic explosive in a sample (par. 14).

Response to Arguments

3. Applicant's arguments filed 30 December 2008 have been fully considered but they are not persuasive.

Applicant argues that Miura et al. do not disclose a linker with 1, 2 or 3 carbon atoms between the functional groups. Applicant's argument is not persuasive because Jacobs et al. and Tao et al. are relied upon for teaching this limitation and Miura et al. is not relied upon for teaching this limitation.

4. Applicant argues that Jacobs et al. do not mention what the length of Y in the NHS-Y-NHS linker with functional groups is and also do not teach that Y is aliphatic hydrocarbon chain. Applicant's argument is not persuasive because although Jacobs et al. is silent about the type of linker Y is, Jacobs et al. is not relied upon for the linker being a certain length or being an aliphatic hydrocarbon chain. Tao et al. is relied upon for teaching this type of linker. Applicant further argues that Jacobs et al. do not teach the significance of the affinity between the antibodies, the antigens bound to the coated surface and the antigens in the test solution or displacement reactions, and that Jacobs et al. implicitly indicates that the affinity of the antibody to the antigen has to be strong to achieve the desired results. Applicant's argument is not persuasive because reversibly bound antibodies.

5. Applicant argues that Tao et al. do not teach or suggest a coated metal surface according to the present invention where the coating consists of a protein layer firmly attached on a metal surface and the protein layer being coupled to a linker firmly attached on a metal surface and the protein layer being coupled to linker molecules that are bound to low molecular weight antigens. Applicant's argument is not persuasive because Miura et al. is relied upon for teaching the metal coated surface with a protein layer. Tao et al. is relied upon only for teaching the linker and is not relied upon for

teaching the coated metal surface according to the present invention. Applicant further argues that Tao et al. teach the protein is part of the binding pair that will enable detection of the target analyte, and in claim 1, the "capture ligand" on the coated surface is the low molecular antigen, not the protein layer. Applicant's argument is not persuasive because Tao et al. is relied upon for teaching the claimed linker and is not relied upon for the ligand or protein layer on the metal surface. Miura et al. and Jacobs et al. are relied upon for teaching this limitation.

6. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Bao-Thuy L. Nguyen/
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March 24, 2009